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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte

AARON W. JANKE, MARY LEE COLE, RONALD W. HEIL, JR.,
JEFFREY T. BARTIG, GARY W. GOEBEL, DOUGLAS A. HEITKAMP,
and RANDALL M. PETERFESO

Appeal 2008-4330
Application 10/650,207
Technology Center 3700

Decided: September 26, 2008

Before ERIC GRIMES, RICHARD M. LEOVITZ, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

REMAND TO THE EXAMINER

This is an appeal under 35 U.S.C. § 134 involving claims to an electrode for implantation into the heart. The Examiner has entered a number of obviousness rejections. We have jurisdiction under 35 U.S.C. § 6(b).

Because the appealed rejections are not set forth in a manner that allows meaningful review, we remand the case to the Examiner to reconsider them in light of the following discussion.

STATEMENT OF THE CASE

Claims 1-8 and 16-19 stand rejected and are on appeal (App. Br. 4).

Claim 1 is illustrative of the appealed subject matter and reads as follows:

1. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:
 - an electrode tip;
 - a mesh screen disposed at a distal end of the electrode tip;
 - a surface at the distal end of the electrode tip;
 - a helix disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface, the helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient;
 - a guiding mechanism for directing movement of the fixation device during travel; and
 - a movement assembly, said movement assembly for providing movement to said fixation device.

The Examiner cites the following documents as evidence of unpatentability:

Grassi	US 4,624,265	Nov. 25, 1986
Heil, Jr. et al.	US 4,819,661	Apr. 11, 1989
Bisping	US 4,886,074	Dec. 12, 1989
Dutcher et al.	US 5,217,028	Jun. 8, 1993
Jammet	US 5,447,534	Sep. 5, 1995
Vachon	US 5,531,780	Jul. 2, 1996
Altman	US 5,551,427	Sep. 3, 1996
Pohndorf et al.	US 5,776,178	Jul. 7, 1998

Ocel et al.	US 5,837,006	Nov. 17, 1998
Struble	US 5,871,531	Feb. 16, 1999
Hoffmann et al.	US 5,902,329	May, 11 1999

The following rejections are before us for review:

Claims 1-5, 7, 8, and 16-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bisping (Ans. 3-6).

Claims 1, 2, 3, 7, 8, and 16-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grassi (Ans. 6-9).

Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Grassi (Ans. 9-10).

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Bisping or Grassi (Ans. 10).

OBVIOUSNESS

“In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.” *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

In rejecting claims 1-5, 7, 8, and 16-19 as obvious over Bisping, the Examiner finds that Bisping discloses a device having all the features of claim 1, “except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant” (Ans. 3). The Examiner’s statement of rejection does not directly cite any prior art to show that these differences would have been obvious to a person of ordinary skill in the art.

Rather, the Examiner's statement of rejection merely states that the missing features were "known in the art" (Ans. 3-4). For example, regarding the coating on the claimed electrode's helix, the Examiner concludes:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Bisping, with . . . the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant . . . since it was known in the art for heart leads to use a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

(*Id.*)

However, the Examiner points to no specific disclosure in the prior art that supports the above assertions regarding the claimed coating's art-recognized advantages. Instead, after essentially asserting that a single reference, Bisping, demonstrates the obviousness of the rejected claims, the Examiner provides a separate listing of five references -- Dutcher, Heil, Altman, Struble, and Pohndorf -- that are asserted to show that the limitations in claim 1 not taught by Bisping were "notoriously well known" elements of the type of electrode disclosed by Bisping (Ans. 4-6).

However, "[w]here a reference is relied on to support a rejection, whether or not in a 'minor capacity,' there would appear to be no excuse for not positively including the reference in the statement of the rejection." *In*

re Hoch, 428 F.2d 1341, 1342 n.3 (CCPA 1970); *see also* MPEP § 706.02(j).

Thus, in the instant case, if the Examiner considers claims 1-5, 7, 8, and 16-19 to be obvious in view of Bisping, Dutcher, Heil, Altman, Struble, and Pohndorf, then the statement of rejection should say so, rather than saying that the claims are obvious over Bisping by itself.

Also, the statement of rejection is self-contradictory because, on one hand, the Examiner initially asserts, in essence, that the rejected claims would have been obvious in view of a single reference, while on the other hand, the Examiner later cites five references in addition to the primary reference as evidence of obviousness. Moreover, because the statement of rejection lists Bisping as the only specific prior art basis for the conclusion of obviousness, it is unclear whether the Examiner is relying on all, or only a few, of the later-cited references; it is also not clear whether those references are intended to be applied alternatively, cumulatively, or in combination to reach the limitations of the claims.

Every one of the appealed rejections suffers from this same deficiency. Specifically, in rejecting claims 1, 2, 3, 7, 8, and 16-19 as obvious over Grassi by itself, the Examiner acknowledges Grassi's failure to disclose an electrode having the mesh and coating recited in claim 1 (Ans. 6), but concludes that an electrode having those features would have been obvious because the claimed elements were "known in the art" (*id.* at 7).

The Examiner then separately cites Dutcher, Heil, Altman, Struble, and Pohndorf to show that the limitations in claim 1 not taught by Grassi were "notoriously well known" elements of an electrode of the type disclosed by Grassi (Ans. 8-9). Again, however, if the Examiner considers

claims 1, 2, 3, 7, 8, and 16-19 to be obvious over Grassi, Dutcher, Heil, Altman, Struble, and Pohndorf, then the statement of rejection should say so, rather than saying that the claims are obvious over Grassi by itself.

Similarly, in rejecting claims 4 and 5 as obvious over Grassi (Ans. 9-10), the Examiner does not cite any prior art to demonstrate the obviousness of the asserted missing elements, a knob and slot in the electrode mechanism, until citing the Bisping, Ocel, and Jammet references in response to Appellants' arguments (*id.* at 15). Again, if the Examiner considers claims 4 and 5 to be obvious over Grassi, Bisping, Ocel, and Jammet, then the statement of rejection should say so, so that the rationale for the rejection is clear.

Similarly, in rejecting claim 6 as obvious over Bisping or Grassi (Ans. 10), the Examiner fails to cite any prior art to demonstrate the obviousness of the asserted missing element, a groove guide in the mesh screen, until citing the Vachon and Ocel references in response to Appellants' arguments (*id.* at 16). Again, if the Examiner considers claim 6 to be obvious over Bisping or Grassi in view of Vachon and Ocel, then the statement of rejection should say so, so that the rationale for the rejection is clear.

Thus, when the Examiner takes this case up for action, if the Examiner is still of the opinion that the claims are obvious, the Examiner should provide a statement of rejection that includes *all* of the prior art references relied on, even those relied on in a minor capacity. Also, the Examiner's statement of rejection should clearly say *where* the references disclose the asserted claim limitations, *and why* one of ordinary skill in the art would have combined *those specific disclosures* with the disclosures in the other references to obtain the claimed invention.

SUMMARY

We remand for further action not inconsistent with this opinion.

REMANDED

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